

APPROVED	O.G. FIG.	
BY	CLASS	SUBCLASS
DRAFTSMAN		

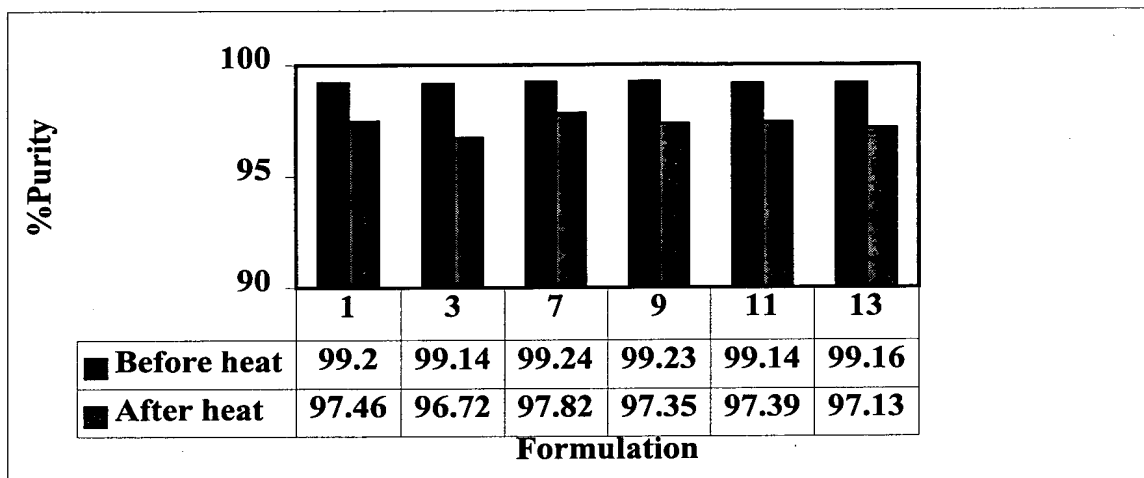
Title: GLP-2 FORMULATIONS

Inventor(s): Indu J. Isaacs

Appl. No.: Not yet assigned

Atty. Docket No. 016777/0454

**Figure 1. Amino acids screening in buffers using heat stress.**



**Formulation**

1. 10 mM Phosphate, 10 mM Glu
3. 10 mM Phosphate, 10 mM Citrate
7. 10 mM Phosphate, 10 mM Ser
9. 10 mM Phosphate, 10 mM Pro
11. 10 mM Phosphate, 10 mM His
13. 10 mM Phosphate, 10 mM Gly

Docket: 2005260

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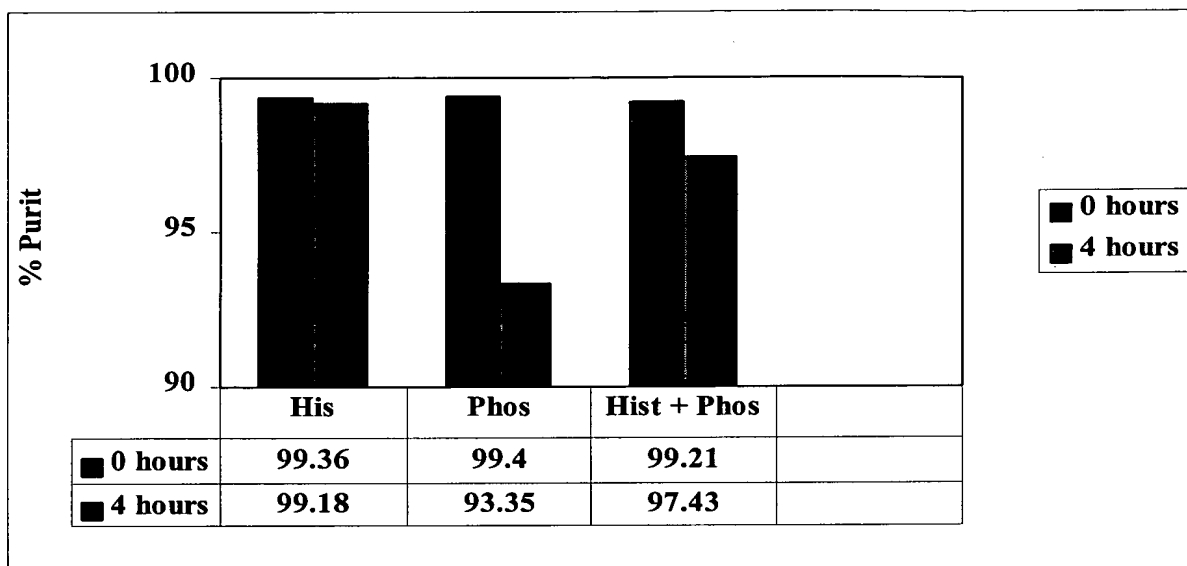
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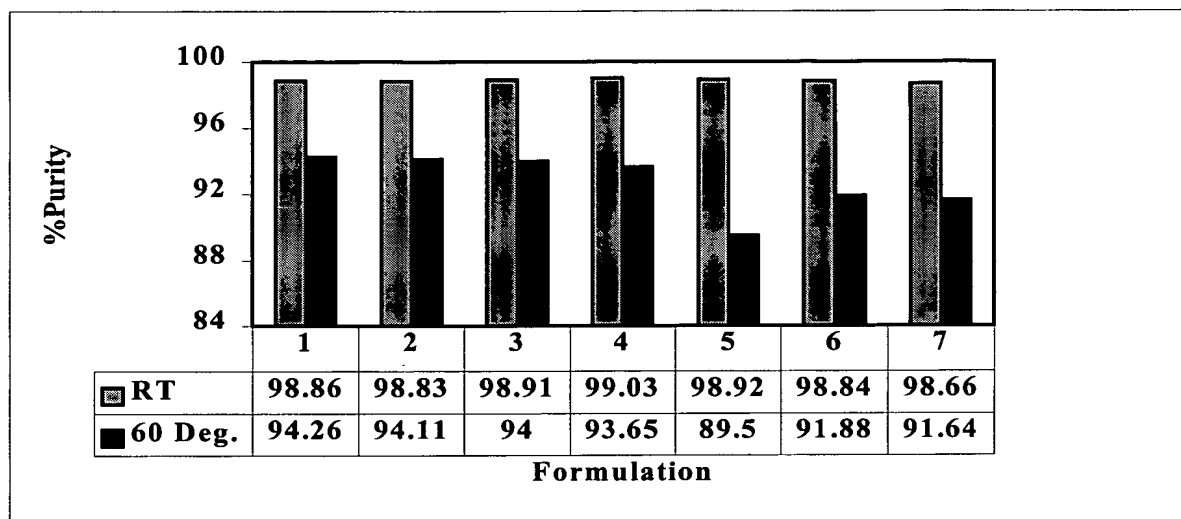
**Figure 2. Screening of buffers using heat stress.**



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Figure 3. Screening of Bulking agents analyzed by RP-HPLC.



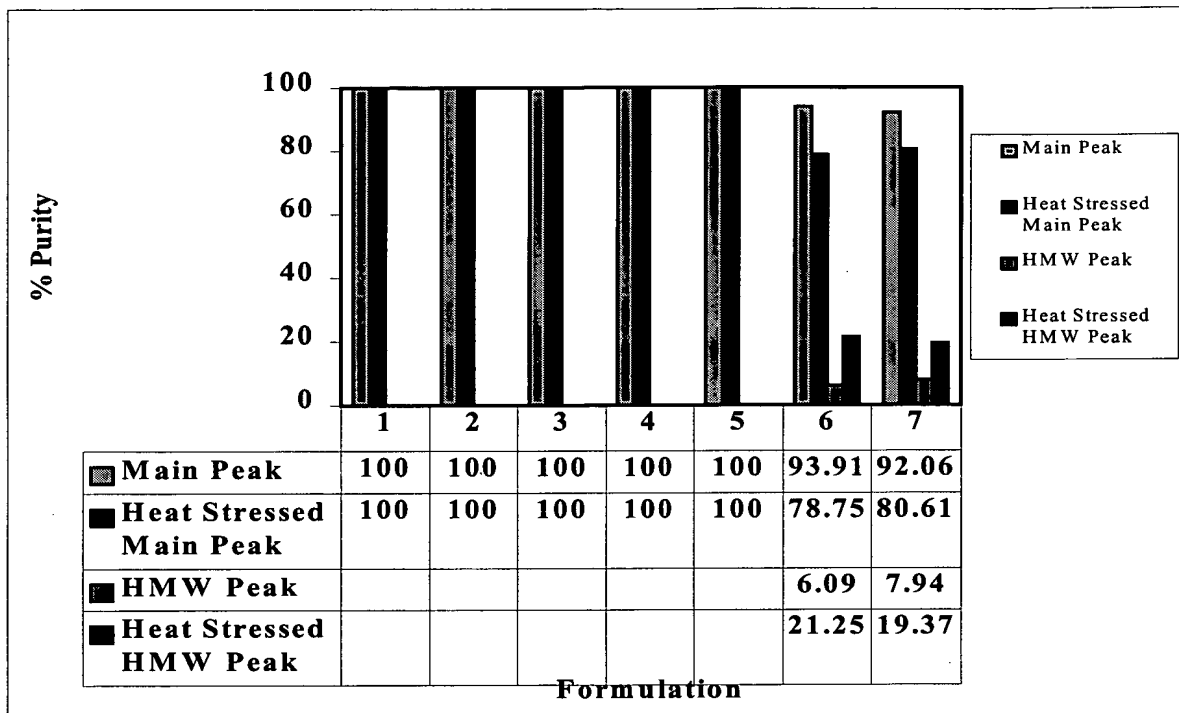
#### Formulation

1. 25 mM Histidine, 35 mM phosphate, 3% Mannitol
2. 50 mM Histidine, 35 mM phosphate, 3% Mannitol
3. 75 mM Histidine, 35 mM phosphate, 3% Mannitol
4. 25 mM Histidine, 25 mM phosphate, 3% sucrose
5. 25 mM Histidine, 25 mM phosphate, 3% trehalose
6. 25 mM Histidine, 25 mM phosphate, 3% maltose
7. 25 mM Histidine, 25 mM phosphate, 3% lactose

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Figure 4. Bulking agents analyzed by SE-HPLC.



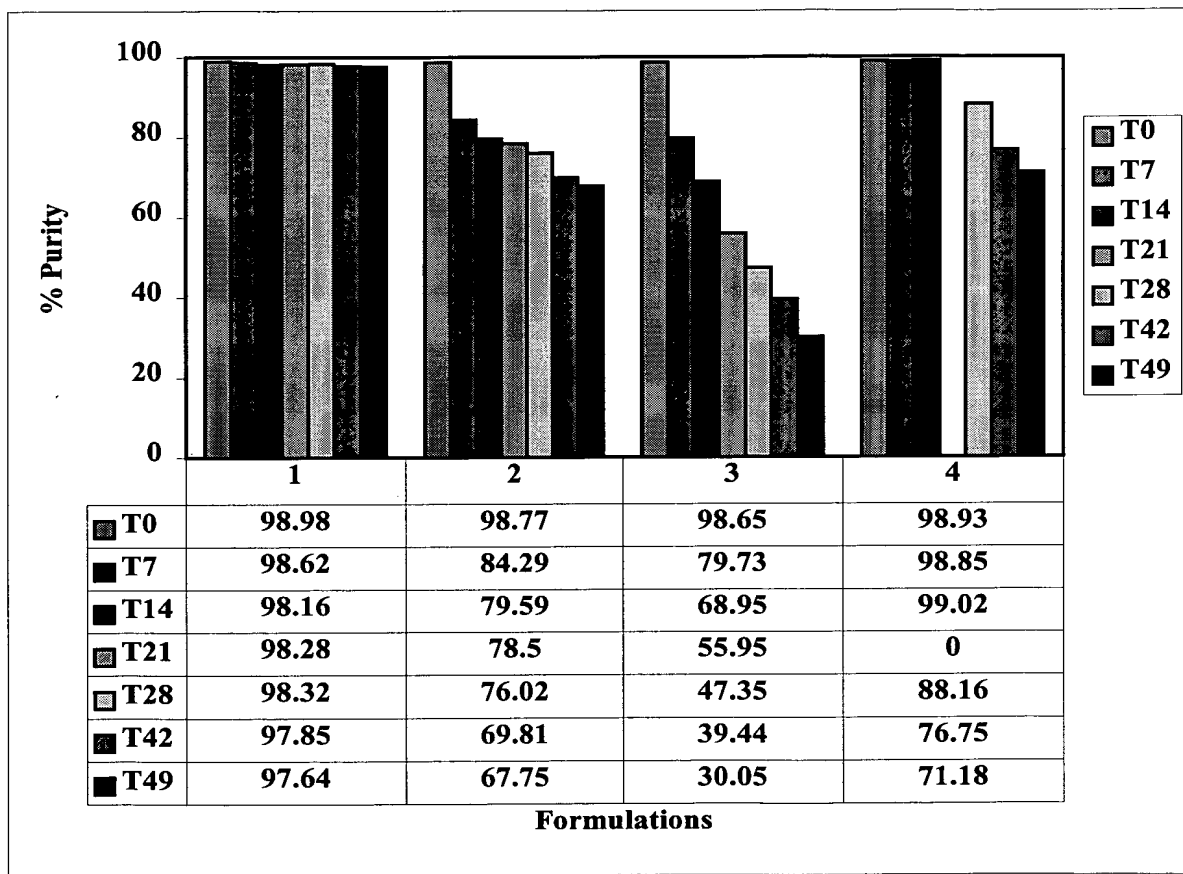
**Formulation**

- 25 mM Histidine, 35 mM phosphate, 3% Mannitol
- 50 mM Histidine, 35 mM phosphate, 3% Mannitol
- 75 mM Histidine, 35 mM phosphate, 3% Mannitol
- 25 mM Histidine, 25 mM phosphate, 3% sucrose
- 25 mM Histidine, 25 mM phosphate, 3% trehalose
- 25 mM Histidine, 25 mM phosphate, 3% maltose
- 25 mM Histidine, 25 mM phosphate, 3% lactose

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Figure 5. Stability of liquid formulations stored at 4 °C.



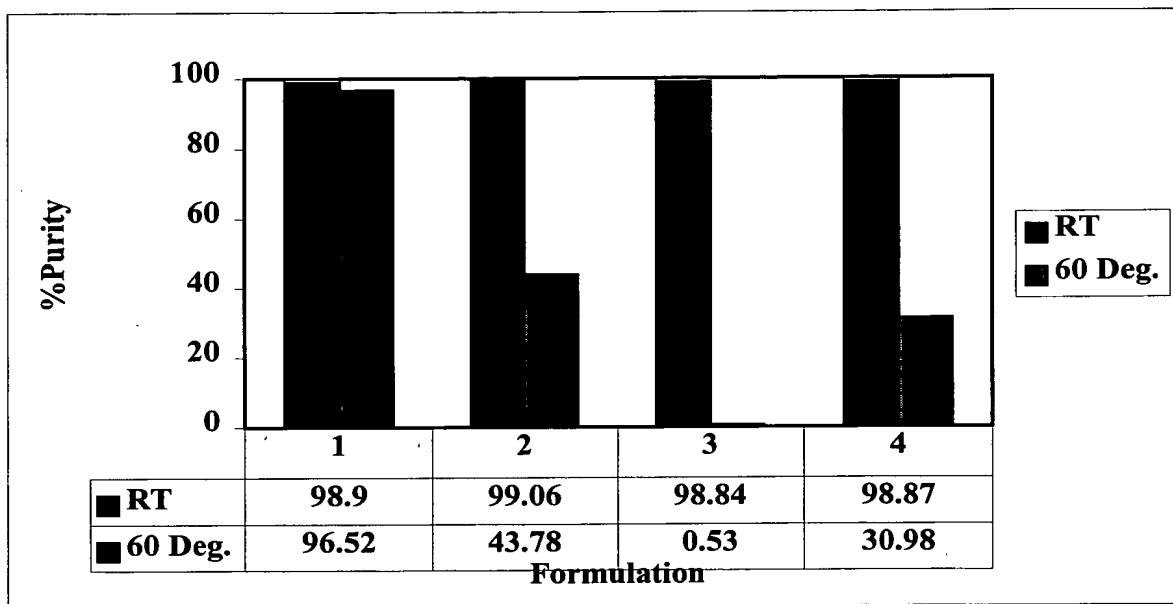
#### Formulations

- 35 mM Phosphate, 50 mM Histidine, 3% Mannitol, pH 7.4
- 35 mM Phosphate, 50 mM Histidine, 5% Sucrose, pH 7.4
- 35 mM Phosphate, 25 mM Lysine, 3% Mannitol, pH 7.4
- 35 mM Phosphate, 25 mM Lysine, 5% Mannitol, pH 7.4

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Figure 6. Heat stressed samples.



#### Formulations

1. 35 mM Phosphate, 50 mM Histidine, 3% Mannitol, pH 7.4
2. 35 mM Phosphate, 50 mM Histidine, 5% Sucrose, pH 7.4
3. 35 mM Phosphate, 25 mM Lysine, 3% Mannitol, pH 7.4
4. 35 mM Phosphate, 25 mM Lysine, 5% Mannitol, pH 7.4